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Supreme Court, U.S.
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No. 98-1373

In The

Supreme Court of the United States

October Term, 1998

C.R. BARD, INC.,

Petitioner,

v.

M3 SYSTEMS, INC.,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

RESPONDENT'S BRIEF IN OPPOSITION

PAUL E. SLATER
Counsel of Record
GREG SHINALL
SPERLING, SLATER & SPITZ, P.C.
55 West Monroe Street
Suite 3300
Chicago, Illinois 60603
312/641-3200

RICHARD D. HARRIS
DICK & HARRIS
181 W. Madison Street
Suite 3800
Chicago, IL 60602
312/726-4000

Counsel for Respondent

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

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PARTIES TO THE PROCEEDING

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of the *Petition for Writ of Certiorari.*

Respondent is M3 Systems, Inc. ("M3"). Pursuant to Supreme Court Rule 29.6 respondent states that it is wholly owned by Manan Medical Products, Inc., which is wholly owned by The Marmon Corporation, which is wholly owned by Marmon Holdings, Inc.

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STATEMENT OF THE CASE

A. The Antitrust Question

1. Statement Of Facts Pertaining To The Antitrust Question

Petitioner, C.R. Bard, Inc. ("Bard"), manufactures automatic biopsy guns. The jury, pursuant to agreed instructions, found that (1) such guns constitute a relevant economic market, and (2) Bard possessed monopoly power in that market. (A 28).[1]

Bard also manufactures biopsy needles which are placed in the automatic gun and shot into a patient to extract tissue for study. The jury found that such needles constitute a second relevant economic market and that Bard obtained monopoly power over that market by the exclusionary conduct described below (A 29).

Respondent, M3 Systems, Inc. ("M3"), manufactured competing biopsy needles usable in Bard's monopoly gun. (2a). In order to avoid Bard's claim that they were infringing Bard's '056 patent, M3 and other competitors redesigned the hubs of their biopsy needles by removing two flanges. (A 15099-116, A 8876-77, A 14504-21, A 7300, A 14968). These flangeless needles worked perfectly well with Bard's gun (A 7295-6, A 8768-73) but did not infringe the '056 patent. (A 13-14, 2a-3a, 79a).

After M3 and other competitors removed the flanges from their needle hubs, Bard modified its automatic gun

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[1] The Joint Appellate Appendix is cited as A ___; Petitioner's Appendix in this Court is cited ___a; and the trial court record is cited as R. ___.

by removing the rear push plate or sled. (A 8327-32, A 8768-73, A 8871-2, A 14517). This prevented the non-infringing, flangeless needles from working in Bard's gun. (A 7174-80, A 8330-2, A 8768-9, A 8876, A 14504, A 15105). Indeed, Bard made this modification explicitly to prevent the use of competitors' non-infringing, flangeless needles with its monopoly gun. (A 8327-32, A 7107-8, A 8768-73, A 8871-72, A 8881-3, A 14517, 86a-87a, Pet. 6). As a Bard memo admits, "the intent of performing this modification is to assure that only needles manufactured according to the Bard patented design can be used with the [Bard gun]." (A 14504).

The removal of the rear push plate from Bard's gun did not improve the gun's performance. The jury was instructed that conduct could "never" be deemed exclusionary if it "involves the introduction of superior products" (A 10120) or "offering better products or services" (A 10113). The jury, however, found Bard's modification of its gun to be exclusionary. (A 29). The appellate court confirmed that "Bard's real reasons for modifying the gun" were to exclude non-infringing, competitive needles from the market and not to make any "improvement" in the gun. (87a-88a). Indeed, the evidence showed that the modification made the gun harder to use and caused doctors to complain. (A 8871-91). Bard's own documents admit that the modification did not improve the gun's performance. (88a, A 14504-5).

Bard not only removed the rear push plate from new guns, but also secretly and without customer permission removed the rear push plate from customer owned guns which were sent to Bard for repair or refurbishment. As a result, the gun owners could no longer use competitors'

non-infringing, flangeless needles after the guns were returned. (A 6859-60, A 8875-6). Customers complained about this conduct and several Bard executives proposed that the gun owners be given the choice of receiving back their unmodified guns. (A 8873-4). This proposal was rejected because Bard "wanted to continue to try to gain market share with our needles." (A 8874). Bard, with a 75% market share in needles, admitted that its intent was to aggressively remove from the field any gun which was compatible with a competitor's flangeless needle so as to "make it difficult for Manan to compete" and to obtain "biopsy dominance." (A 8882-3, A 15107).

Bard also placed a prominent warning label on all modified guns. This label stated: "Caution. Use only Bard Biopty-cut biopsy needles with this instrument." (A 8360). This was done even though there were no instances of a non-Bard needle injuring a patient due to its use with the Bard gun. (A 7174-80, A 7185-6). Bard admitted at trial that due to malpractice concerns no doctor would use a competing needle with Bard's gun after the warning label appeared. (A 8359).

2. The Antitrust Ruling In The District Court

The jury was instructed that M3's monopoly leveraging theory was that Bard, by modifying its gun so as to preclude use of competing needles, had used monopoly power over the gun market to obtain monopoly power over the needle market. (A 10104, A 10115-8). This theory was plainly set forth in the pre-trial order, which, pursuant to Federal Rule of Civil Procedure 16(e), "shall

control the subsequent course of the action." (A 534 R. 57, p. 14).

The monopoly leveraging instructions were agreed and not objected to by Bard. (88a). The jury was told that mere possession of monopoly power is not unlawful (A 10114); that a violation results only if monopoly power is obtained by "exclusionary acts" and that making improved or better products "can never be found to be exclusionary." (A 10120-1). The jury nevertheless found Bard's conduct exclusionary and returned a verdict for M3 on the monopoly leveraging claim. (A 29).

At the close of M3's case, Bard moved for judgment as a matter of law ("JMOL") on several of M3's antitrust theories. Bard's motion, however, did not utter a single word about the gun modification/monopoly leveraging theory. (A 5270-357, R. 302). After the jury returned its verdict, Bard renewed its motion for JMOL. (A 5270). Despite the fact that arguments not made in the pre-verdict motion for JMOL are deemed waived,[2] Bard argued that the gun modification verdict was defective, but only due to an asserted insufficiency of the evidence to meet the elements in the agreed instructions. (A 5354-6 R. 302, pp. 79-81). Bard's motion was denied. (A 2-3).

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[2] *See* F.R.C.P. 50; *Kutner Buick, Inc. v. American Motor Corp.*, 848 F.2d 614, 617 (3rd Cir. 1989); *Kinzenbrew v. Deere & Co.*, 741 F.2d 383, 387 (Fed. Cir. 1984).

3. The Antitrust Ruling In The Federal Circuit

In its main brief to the Federal Circuit, Bard devoted only two pages to M3's three antitrust theories. As in the trial court, Bard did not challenge the viability of M3's legal theories. Rather, Bard's only attack on the antitrust judgment was that "there was no substantial evidence supporting any of [M3's antitrust] theories." (Bard App. Br. 48-49).

With regard to the monopoly leveraging theory on which *certiorari* is now sought, Bard's argument consisted of exactly two sentences. In conclusory fashion, Bard argued that the gun modification could not be unlawful because under Bard's rejected view of the evidence, M3 could still compete. (Bard App. Br. 49-50).

The Federal Circuit opinion, authored by Judge Bryson and joined by Chief Judge Mayer, affirmed that Bard had used its monopoly power over biopsy guns to obtain monopoly power over biopsy needles. (86a-89a). The Court pointed out that on appeal Bard did not challenge the adequacy of M3's legal theory, but merely "the sufficiency of the evidence to support the jury's verdict." (86a). The Court then held that the jury had been presented with "evidence that Bard modified its Biopty gun to prevent its competitors' non-infringing, flangeless needles from being used in Bard's guns." (86a). The majority also approved the jury's findings that biopsy needles constituted a relevant market; that Bard had obtained monopoly power in that market; and that it had done so through exclusionary conduct. (86a-87a).

The majority noted that in order to prevail on its monopoly leveraging theory that M3 had been required to prove that the change in Bard's gun had been made "for predatory reasons, *i.e.*, for the purpose of injuring competitors in the replacement needle market, rather than for improving the operation of the gun." (87a). While Bard disputed this and other evidence the majority held that:

> The evidence was sufficient to support the jury's verdict on that point and also support the jury's conclusion that Bard maintained its monopoly position by exclusionary conduct, to wit, modifying its patented gun in order to exclude competing replacement needles.

(87a).

Judge Newman wrote a dissenting opinion. It is based on arguments never advanced or preserved by Bard in the trial court or on appeal. Because these arguments had never been briefed, Judge Newman was left to make assumptions about the facts and record below – many of which are simply incorrect.

For example, Judge Newman assumed that Bard's gun modification was a product "improvement" and states that it would be "novel and pernicious" to allow a product improvement to constitute an antitrust violation. (58a-59a). The jury, however, was instructed that "offering better products or services" or the "introduction of superior products" can "never be found to be exclusionary" (A 10113, A 10120-1) and, as the majority opinion points out, Judge Newman's "premise . . . is contrary to the jury's verdict, which was supported by the evidence."

(87a-88a). Indeed, the evidence showed that Bard's gun modification reduced its performance. (A 8871-3).

Similarly, Judge Newman opines that the jury instructions should have explained in more detail the lawful right of a patentee to exclude others from making the patented invention. (57a, 62a). Exactly what Judge Newman believes the instructions should have said is unknown and, as the majority opinion points out, Bard did not object to the instructions at trial or on appeal. (88a). As a result the majority held "the legal sufficiency of the jury charge on the antitrust issues is not properly before us on appeal." (88a).

Judge Newman further states that by using a simple adapter clip, M3's customers could have continued to use M3's flangeless needles in Bard's modified gun. (58a). Indeed, Judge Newman states that the need to use the adapter "is the antitrust ill of which M3 complained." (*Id.*). This argument was never advanced by Bard.

In fact, after Bard modified its monopoly gun, M3 did make one prototype of a an adapter clip that would allow its non-infringing flangeless needle to work in Bard's modified gun. (A 9162, A 9136-7). The clip, however, was unsafe. It could be easily dislodged and therefore presented a danger of patient injury. As a result, only the one prototype clip was ever made and none were ever sold or distributed. (A 9056-7, A 9136-7, A 9340-1).

Finally, Judge Newman states that Bard's monopoly power over the needle market is based on its '056 patent and is therefore lawful. (58a). This conclusion completely ignores that (1) the trial and appellate courts both held the '056 patent to be invalid and (2) M3's flangeless

needle did not infringe the '056 patent in any event. (A 14). M3, therefore, would not have been excluded from the market by the '056 patent even if it had been valid. Only modification of Bard's gun could accomplish that result.

4. Bard's Petition for Rehearing

After the Federal Circuit affirmed the monopoly leveraging claim, Bard filed a Petition for Rehearing and Suggestion for Rehearing In Banc. Bard's petition quoted extensively from Judge Newman's dissenting opinion and argued "Judge Newman's analysis is correct." (Pet. Reh. 11-12). This was the first time – either at trial or on appeal – that Bard had asserted *any* of the arguments raised in Judge Newman's dissent.

The petition for rehearing and suggestion for rehearing in banc were both denied. (90a-91a). Circuit Judge Gajarsa, joined by Judge Clevenger, wrote an opinion concurring in that order. (92a). In their concurring opinion they pointed out that no "fundamental issues at the intersection of patent law and antitrust law were being decided" by the Federal Circuit. (92a). In addition, their concurrence states (93a):

> the *only* argument Bard made on appeal regarding the antitrust violation was directed to the sufficiency of the evidence on this issue. Bard did not argue that modification of a patented product . . . cannot, as a matter of law, constitute an antitrust violation. Nor did Bard challenge the jury instructions. . . . In light of our limited review of jury findings, the majority affirmed the jury verdict based on its determination that

there was substantial evidence to support the verdict.

Consequently, this case does not establish or endorse a new antitrust theory.

B. The "On-Sale" Bar Patent Question

Bard attempts to mislead the Court into believing that the Federal Circuit's use of the "totality of the circumstances" test in determining whether three offers for sale were invalidating, caused it to decide that question differently than it would have if it had employed the more recent test set forth in *Pfaff v. Wells Elecs., Inc.*, ___ U.S. ___, 119 S. Ct. 304 (1998). In so doing, Bard suggests that the Federal Circuit was not aware of this Court's decision in *Pfaff* at any time during its consideration of the on-sale bar issue in this case. That is simply untrue.

First, in anticipation of *Pfaff*, the Federal Circuit panel expressly affirmed facts that meet the *Pfaff* test. Second, *after* this Court rendered its decision in *Pfaff*, the entire Federal Circuit considered Bard's Petition for Rehearing and Suggestion for Rehearing In Banc, which requested the court to re-evaluate the three invalidating offers for sale in this case in light of the issues raised by *Pfaff*. (Pet. Reh. 8-9). In ruling that rehearing was neither appropriate nor necessary, the Federal Circuit implicitly confirmed that this Court's decision in *Pfaff* does not require a different result than the one reached earlier by the appellate panel.

1. Statement of Facts Pertaining to the Patent Question

Under the *Pfaff* test, the facts in this case present a much stronger basis for finding an invalidating offer for sale and an invalidating actual commercial sale than do the facts in *Pfaff* – where the offer was still held to be invalidating. While *Pfaff* involved only a single sale of an invention *prior to the development of any physical embodiment of the invention*, the present case involves the following:

- an offer to sell the invention based upon detailed drawings *and existing commercial prototypes* that were successfully tested (the Phelps transaction) (70a-72a, 75a);
- a second invalidating *offer to sell* bulk quantities of the *existing physical embodiment* of the invention at volume discount rates (81a, 84a-85a); and
- the *sale* (*and delivery*) of a commercial quantity of *operable* needles and guns (*i.e.*, 250 needles and 10 guns) (81a, 84a-85a).

Simply put, each of these offers for sale or actual commercial sale meets and surpasses the *Pfaff* test for invalidating Bard's patent.

a. The November 12, 1984 Offer for Sale to Dr. Phelps

The offer to sell the second generation system to Dr. Phelps was a clear attempt to commercialize not only the biopsy gun but also the '056 needle. On September 25, 1984, Dr. Phelps wrote to Bard's predecessor, Radiplast,

seeking information about an earlier generation device pictured in a brochure. (A 13909). On November 12, 1984, Mr. Engstrom responded on behalf of Radiplast by offering to sell Dr. Phelps the "generation No. 2" (*i.e.*, the '056) biopsy gun and needles. In his letter to Dr. Phelps, *more than twenty months prior to the filing date of the patent in question*,[3] Mr. Engstrom stated:

> If you do not want to wait until we have our representation in USA arranged, *you can allways [sic] order the device directly from us. Our price for the device is SEK 9.900, – and for the needles SEK 75, – /ea.*
>
> The device is reusable and can be autoclaved. Very little service has to be done on the device due to reliable design. The needles are disposable and are designed to suit the device. (A 13911).

Actual physical embodiments of these needles had been tested and approved by Radiplast one month before Engstrom sent his offer of sale. On September 28, 1984, the manufacturer transmitted twelve physical samples of the needles expressly for the purpose of testing. (A 13945). On October 14, 1984, Mr. Engstrom wrote to the manufacturer:

> Biopsy needles: Enclosed please find our order for tooling and engineering. We approve your design of the plastic parts. (A 13947).

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[3] The patent in question was applied for on July 30, 1986 and originally issued as the '154 patent. It reissued in 1992 as the '056 patent. (5a-6a).

Accordingly, at the time of the offer to sell needles to Dr. Phelps, a physical, operable construction of the needle had been made, tested, and approved; and production tooling had been ordered.

b. Radiplast's Invalidating Sale of 10 Operable Guns and 250 Needles to a Potential Distributor

In June 1985, Radiplast again attempted to commercialize its invention more than one year before the filing date of the '154 patent. At that time, Radiplast sold and delivered 10 biopsy guns and 250 needles to a potential U.S. distributor, Pharmaseal, as part of its "marketing strategy." (A 8166-7, A 13825-27). Radiplast issued invoices for the 10 biopsy guns and for the 250 needles to Pharmaseal and requested payment. (A 13829-31). Moreover, Pharmaseal acknowledged to doctors and hospitals that it would be "conducting this field trial as a potential sales/distribution system for the Radiplast" needles. (A 13974). Therefore, the Pharmaseal "market study" itself constituted an invalidating sale and the actual delivery of commercially useable needles long before the critical date.

c. Radiplast's Invalidating Bulk Sale of Needles

Radiplast again commercialized its invention more than one year prior to the filing date of the '154 patent on January 21, 1985. At that time Radiplast offered via telex to sell Pharmaseal 10,000, 20,000 and 50,000 needles at volume discount rates:

> In quantities from 500 – 4000 PCS of the reusable device the price will go down to approx. 500 – 200 US DLRS/ea. For the needles the price will be for 10000 4.6 US DLRS/ea. 20000 4.3 US DLRS/ea. and for 50000 4.20, all bulk packed. Orders should be sent to us for both reusable and disposable device. Delivery of the needles will be made from Hart Ent. Direct to you. (A 13679).

The prices quoted by Radiplast not only represented a firm offer, but also a 60% profit on the needles for Radiplast. (A 8292-4, A 13929-30, A 13679). This bulk sale promotion constituted the very type of invalidating offer to sell commercially available products that § 102(b) is intended to prevent and easily meets the standard set forth in *Pfaff*.

2. The Patent Ruling In The District Court

The jury was instructed without objection on the issue of the on-sale bar and rendered special verdicts in favor of M3 on each asserted patent claim. (A 9). In particular, the jury found that the '056 patent was invalid and not infringed "because the claimed invention was . . . on sale in the United States more than one year prior to the actual date of filing of the application. . . . " (*Id.*).

3. The Patent Ruling In The Federal Circuit

Notwithstanding Bard's mischaracterizations, a majority of the Federal Circuit panel held that the '056/'154 patent was invalid due to the two offers to sell

and one actual sale referenced above. As stated by Chief Judge Mayer, the Federal Circuit "*may affirm the invalidity verdict on either basis.*" (67a) (emphasis added). Moreover, Judge Bryson succinctly stated "I agree with Chief Judge Mayer that the '056 patent is invalid under the 'on-sale bar' of 35 U.S.C. § 102(b)." (79a).

At the time the Federal Circuit issued its ruling in this case, it was well aware that *Pfaff* was awaiting decision in the Supreme Court. The opinions of both Chief Judge Mayer and Judge Bryson clearly anticipate and track the elements of the *Pfaff* test. Chief Judge Mayer segmented his analysis into (1) whether Bard's actions constituted an offer ("I. Offer for Sale") and (2) the status of the invention at the time the offer was made ("II. Offer of the Claimed Invention"). This is identical to the analysis required by *Pfaff*.

In conducting that analysis, both Chief Judge Mayer and Judge Bryson held that the offered products were reasonably expected to work for their intended purpose. (75a-76a, 81a-85a). For example, Chief Judge Mayer held that "the evidence suggests at the very least that Radiplast had reason to expect in November 1984, that its needle would work for its intended purpose . . . " and "that Radiplast had more than a mere conception from which it was working towards development." (77a). In addition, Chief Judge Mayer held that Mr. Engstrom made a commercial offer for sale to Dr. Phelps, stating "Engstrom's letter [of November 12, 1984] is a clear offer for sale of the second generation device and the biopsy needles." (72a). Chief Judge Mayer also held that "the alterations made after the offer for sale to Phelps did not address inventive aspects of the '056 patent's new biopsy

needle" (75a) and concluded that "Bard's evidence shows nothing beyond unclaimed mechanical adjustments to the needle design." (77a).

Judge Bryson similarly found invalidating commercial offers for sale of a device that was ready for patenting: "It is undisputed that the June 1985 transaction constituted a sale and that the needles sold at that time embodied the invention of the '056 patent." (81a). Judge Bryson also considered the offer to sell up to 50,000 needles to Pharmaseal and stated "[t]he offer of such large quantities of needles was clearly for commercial, rather than experimental, purposes, and by June 1985 it was clear that the needles that were being offered to Pharmaseal embodied the later-claimed invention." (84a). Judge Bryson also found that experimentation was not required and that Radiplast knew the needles would work for their intended purpose. (81a-83a). Simply put, the needle was ready for patenting. Indeed, it had already been *reduced to practice*, at the time each commercial offer for sale was made.

4. Bard's Petition for Rehearing

This Court decided *Pfaff* on November 10, 1998. Bard's Petition for Rehearing and Suggestion for Rehearing In Banc was not denied until December 7, 1998 – almost a month later. With the benefit of the *Pfaff* decision, the original panel and the circuit as a whole declined to rehear Bard's arguments. (90a-91a). This action by the Federal Circuit implicitly confirms that the

panel's original holding with regard to the on-sale bar issue is not inconsistent with *Pfaff*.

REASONS FOR DENYING THE WRIT

A. The Antitrust Question

The petition does not allege a conflict between the opinion of the Federal Circuit and any other circuit or this Court on the antitrust issue. Apparently Bard's request for review is based on Supreme Court Rule 10(c), which allows for review if "a United States Court of Appeals has decided an important question of federal law that has not been, but should be, settled by this Court."

The antitrust question on which petitioner seeks review, however, was not preserved and was not before the appellate court. As a result, the Federal Circuit plainly stated that the question of whether the modification of a patented product can ever violate the antitrust laws was not being decided. Furthermore, M3's fact-bound monopoly leveraging claim is not a new antitrust cause of action; nor are any novel and critical issues pertaining to the intersection of the patent and antitrust laws presented by the petition.

1. Bard requests that this Court consider whether a patentee with monopoly power may modify his patented product so as to monopolize a second relevant product market without violating the Sherman Act. At trial, however, Bard requested no jury instructions on this subject and did not object to the conventional antitrust instructions given. In its main appeal brief, Bard did not raise

this subject and the majority opinion of the Federal Circuit explicitly stated that Bard had not raised and the court was not deciding such question. (88a). Rather, the Federal Circuit explicitly stated that it was only deciding that there was a sufficient evidentiary basis for the jury to return a verdict for M3 on its monopoly leveraging claim pursuant to the unchallenged instructions given. (*Id.*).

Similarly, in denying rehearing in banc, Judges Gajarsa and Clevenger made clear that the Federal Circuit (1) did not have before it and had not decided the antitrust question on which petitioner seeks review; (2) had decided only the fact-bound question of whether the evidence in this case was sufficient to sustain the verdict under the instructions given; and (3) that as a result "this case does not establish or endorse a new antitrust theory." (92a-94a).

This Court has consistently refused to decide questions of law not decided by an appellate court or not preserved by objection to the instructions at trial. *City of Springfield v. Kibbe*, 480 U.S. 257, 258-59 (1987) (writ of *certiorari* dismissed because "we ordinarily will not decide questions not raised or litigated in the lower courts," especially where party seeking to argue the issue failed to object to the jury instructions); *E.E.O.C. v. Federal Labor Relations Authority*, 476 U.S. 1924 (1986) (writ of *certiorari* dismissed because "our normal practice . . . is to refrain from addressing issues not raised in the court of appeals."); *Addickes v. S.H. Kress & Co.*, 398 U.S. 144, 147 n. 2 (1970) (Supreme Court will not review a question not pressed or passed on in the court below).

2. The question of whether the owner of a valid patent who enjoys monopoly power in the market for the patented product can modify his patented product so as to monopolize a second market is not raised by the decision below for yet another reason. Here, the '056 patent which covered Bard's automatic gun and needle (A 13589) was held invalid due to an on-sale bar by both the trial and appellate courts. (2a-3a). Therefore, Bard had no right, incident to a *valid* patent, to exclude competitors from making biopsy needles. Despite this fact, Bard blithely assumes throughout its petition that the '056 patent is valid and that the application of the antitrust laws therefore has to be altered to accommodate the lawful right of a patentee to exclude infringers.[4]

Furthermore, the trial court held that M3's flangeless needle did not infringe the '056 patent. (A 14-17).[5] Thus, even if the '056 had been found valid, it provided no lawful basis to exclude from the relevant market M3's non-infringing, flangeless needles.

3. Bard states that it modified its gun "within the scope of the ['056] patent." Nothing could be further from the truth. Bard modified its gun by removing the rear

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[4] *See, e.g.*, Petition at 15, where Bard argues that the Federal Circuit created a new antitrust cause of action by "disregarding Bard's rights as a patentee [of the '056 patent]"; *see also* Petition at 16-17, where Bard argues that the '056 patent gave it the lawful right "to exclude competitors from making, using or selling the needles used with Bard's patented modified device."

[5] Because the Federal Circuit found the '056 patent invalid it had no need to reach the question of whether the trial court erred in holding that M3's flangeless needles did not infringe that patent. (3a).

push plate or sled. (A 8327-32, A 8768-73, A 8871-2, A 14517). The '056 patent had 23 claims. (A 13589). The rear push plate, however, is not a claimed feature in any one of them. In fact, there is not one single word pertaining to the rear push plate in the '056 patent.

It is therefore clear that, even if the '056 patent were valid (which it was not), Bard modified an unpatented feature of its gun for the sole purpose and with the effect of monopolizing a second relevant market. Whatever antitrust issues this conduct raises, it has nothing to do with the intersection of the patent and antitrust laws because the anticompetitive product modification was with regard to a feature on which no patent rights were ever claimed.

4. This Court has long held that use of monopoly power in one market to obtain monopoly in a second market is a violation of § 2 of the Sherman Act. For example, in *United States v. Griffith*, 334 U.S. 100, 107-08 (1948), this Court held that the use of monopoly power in certain geographic markets to "beget monopoly" in other markets to be illegal, stating: "the use of monopoly power, however lawfully acquired, to foreclose competition, to gain a competitive advantage, or to destroy a competitor, is unlawful." *Accord*, *Otter Tail Power Co. v. United States*, 410 U.S. 369 (1973) (use of monopoly power over power transmission lines to obtain monopoly over retail distributor held unlawful); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1065 (3d Cir.), *cert. denied*, 439 U.S. 838 (1978) (use of monopoly power over patented products to exclude competitor from other product markets held unlawful); *Alaska Airlines v. United Airlines*, 948 F.2d 536, 548 (9th Cir. 1996) (use of monopoly power "in

the first market to acquire or maintain a monopoly in the second market" violates § 2).

In this case, Bard had monopoly power over the gun market. Without that power, Bard would have lost gun sales if it reduced the quality of its gun or modified the gun so as to exclude the use of competing needles which customers wanted to use. Because it enjoyed monopoly power over the gun, consumers were without adequate gun alternatives and had to continue to purchase the Bard gun and therefore to use only the Bard needle. This is a classic use of monopoly power over one market to exclude competitors from and obtain a monopoly in a second market. There is nothing novel about this theory. It is conventional and well-established antitrust doctrine which does not necessitate review by this Court.

5. Bard also claims that it is novel and unprecedented to hold that one who modifies a product for the purpose and with the effect of monopolizing a related market has violated the Sherman Act. Even if Bard had preserved this argument (which it has not), it is without merit.

For example, in *In re IBM Peripheral EDP Devices Antitrust Litigation*, 481 F.Supp. 965, 1003 (N.D. Cal. 1979), *aff'd sub nom., Transamerica Computer Co. v. International Business Machine Corp.*, 698 F.2d 1377 (9th Cir. 1983), the court addressed product changes by a monopolist and stated:

> if the only purpose and effect of the change was to gain a competitive advantage in the terminal market (where the monopolist lacked monopoly

> power), that use of monopoly power would be condemned.
>
> * * *
>
> If the design choice is unreasonably restrictive of competition, the monopolist's conduct violates the Sherman Act.

Accord, Northeastern Telephone Co. v. American Telephone and Telegraph Co., 651 F.2d 76, 94-96 (2d Cir. 1981) (intentionally designing couplers to impede competition in the terminal market held to be a predatory act that would support Sherman Act violation). *See also* 1 ABA Antitrust Law Developments, 286 (4th ed. 1997) (where evidence indicates that product modification does not improve performance or lower cost and sprang from anticompetitive motives, violation may result).

In this case, the evidence showed and the jury found that Bard's modification of the biopsy gun did not improve performance or make the product better. It made the product worse. Bard's sole intent was to exclude the competing, non-infringing, flangeless needles from the market. (A 14504-05, Pet. 6). There is nothing novel or pernicious about holding such blatantly anticompetitive conduct illegal.

B. The Patent Question

1. Bard Has Failed to Allege A Proper Basis for Review of the Patent Holding

Bard's Petition fails to advance any cognizable basis for reviewing the patent decision below. In particular, Bard cannot allege that the Federal Circuit has "so far

departed from the accepted and usual course of judicial proceedings" or that it has "decided an important question of federal law that has not been, but should be settled by this Court or has decided an important federal question in a way that conflicts with relevant decisions of this Court." Supreme Ct. Rule 10(c). Rather, Bard merely intimates that the Federal Circuit's decision is incorrect even after it was reviewed by the entire court *subsequent* to this Court's decision in *Pfaff*. As detailed above, however, the facts and circumstances of this case far exceed the test set forth in *Pfaff*.

2. The Decision Below Is Consistent with *Pfaff*

Pfaff holds that in order to invalidate a patent under 35 U.S.C. § 102(b) that prior to the critical date there must be 1) a commercial offer for sale; and 2) the device must be ready for patenting – meaning that it has either been reduced to practice or drawings or descriptions exist which are capable of enabling one skilled in the art to practice the invention. *Pfaff*, ___ U.S. at ___, 119 S. Ct. at 312.

While the patentee in *Pfaff* did not have a prototype or reduction of the invention to practice until *after* the critical date, this Court still held that the device was offered for sale *prior to* the critical date due to the existence of drawings that were sufficiently clear and precise so as to enable one skilled in the art to understand the device and put it into operation. Even in the absence of a prototype, *Pfaff* held that the device set forth in the drawings could be expected to work for its intended purpose

and that there was sufficient disclosure to allow for the filing of a patent application. *Id.* at 309-10. (A 1645).

The present facts go well beyond what is required by *Pfaff*. First, the Federal Circuit clearly and explicitly held that Radiplast's multiple offers for sale were commercial offers for sale as required by *Pfaff*. Second, unlike *Pfaff*, Radiplast not only had detailed drawings but had actually *reduced the invention to practice* in the form of tested and approved prototypes that were known to work for their intended purpose well before the critical date.

Accordingly, the decision of the Federal Circuit – which that court declined to reconsider after *Pfaff* was decided – is not at all inconsistent with any decision of this Court.

CONCLUSION

For the reasons given above, respondent respectfully submits that the Petition should be denied as to both the antitrust and patent questions on which review is sought.

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Respectfully submitted,

PAUL E. SLATER
Counsel of Record
GREG SHINALL
SPERLING, SLATER & SPITZ, P.C.
55 W. Monroe Street
Suite 3300
Chicago, IL 60603
(312) 641-3200

RICHARD D. HARRIS
DICK & HARRIS
181 W. Madison Street
Suite 3800
Chicago, IL 60602
(312) 726-4000

Attorneys for Respondent
M3 Systems, Inc.